FEB 0 4 2013

Exhibit F 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: K122046

Statement

Wrist Pulse Oximeters MD300W4 is a modification device to Wrist Pulse Oximeter MD300W (K081125). Their differences between them are listed below:

	MD300W4	MD300W
Display Creen	OLED	Segment LCD
Transmission mode	USB and GPRS	USB
Power supply	lithium-ion rechargeable battery	1 AAA
Enclosure	133mm×63mm×33mm	60mm×50mm×20mm

1. **510(k) Owner's Information**

Establishment Registration Number: 3005569927

Beijing Choice Electronic Technology Co., Ltd.

Room 1127-1128 Building B, Bailangyuan

Fuxing Road, No. A36,

100039 Beijing, China

Contact Person: Mr. Lei Chen /Quality Director

Phone: +86-10-88790480

Fax: 215-4052545

Email: cc@choicemmed.com

2. **Prepared Date:** Aug. 8, 2012

3. **Proposed Device Information**

Device Common Name: Pulse Oximeter

Device Trade Name: Wrist Pulse Oximeter

Model: MD300W4

Classification Name: Oximeter

Class: II

Regulation Number: 21 CFR 870.2700

Product Code: DQA

Panel: Anesthesiology

4. Predicate Device

Wrist Pulse Oximeter MD300W (K081125)

Beijing Choice Electronic Technology Co., Ltd.

Room 1127-1128 Building B, Bailangyuan

Fuxing Road, No. A36

100039 Beijing, China

5. Device Description

The proposed device MD300W4 consists of MCU circuit, power supply circuit, SpO2 module circuit, display circuit, Flash memory circuit, GPRS module circuit, charging circuit, real-time clock circuit, button circuit.

It can measure, store, review and display the SpO2% and pulse rate value, time, ID number, pulse bar and battery power status, the connection of probe, and transmit data by GPRS or USB cable.

The power supply is 4.2V Li-battery with capacity 1250mAh. The device can not be used to measure when it charges for the Li- battery.

The Pulse oximeter works by applying a sensor to a pulsating arteriolar vascular bed. The sensor contains a dual light source and a photodetector. The one wavelength of light source is 660 nm, which is red light; the other is 940 nm, which is infrared light.

Skin, bone, tissue, and venous vessels normally absorb a constant amount of light over time. The photodetector in probe collects and converts the light into electronic signal which is proportional to the light intensity. The arteriolar bed normally pulsates and absorbs variable amounts of light during systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO2.

The proposed device has one model detachable sensor as the accessory of which the skin-contacting material is silicon. It is listed below:

M-50G (510(k) number: K082487)

The proposed device is not for life-supporting or life-sustaining, not for implant. The device

or probe is not sterile and does not need sterilization or re-sterilization. The device is for prescription. The device does not contain drug or biological products.

The device is software-driven and the software validation is provided in Section 14 Software on page 14-1.

6. Comparison list of the technological characteristics

ITEM	Proposed Device Wrist Pulse Oximeter MD300W4	Predicate Device Wrist Pulse Oximeter MD300W (K081125)
Composition	A main unit, SpO2 sensor	A main unit, SpO2 sensor
Design principle	Skin, bone, tissue, and venous vessels normally absorb a constant amount of light over time. The photodetector in probe collects and converts the light (660nm red light and 940nm near infrared light) into electronic signal which is proportional to the light intensity. The arteriolar bed normally pulsates and absorbs variable amounts of light during systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO2.	Skin, bone, tissue, and venous vessels normally absorb a constant amount of light over time. The photodetector in probe collects and converts the light (660nm red light and 940nm near infrared light) into electronic signal which is proportional to the light intensity. The arteriolar bed normally pulsates and absorbs variable amounts of light during systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO2
Patient Contact Material	Medical Silica gel and Nylon	Medical Silica gel and Nylon
Display unit specification	OLED	Segment LCD
Working time	Work for 10h continuously	Work for 12h continuously
Power	4.2V Li-battery	1 *AAA
Display Parameter	SpO2, pulse rate	SpO2, pulse rate
SpO2 display range	0%-100%	0%-100%
SpO2 measuring range	70%-100%	70%-100%
SpO2 Resolution	1%	1%
SpO2 Accuracy	70%-100%±3%,	70%-100%±3%,

	90%-100%±2%, 80%-90%±3%, 70%-80%±3%, <70% unspecified	90%-100%±2%, 80%-90%±3%, 70%-80%±3%, <70% unspecified
PR Measuring Range	30～235bpm	30～235bpm
PR resolution	1bpm	1bpm
PR accuracy	±2% or 2 bpm, whichever is greater	30-99bpm, ± 2 bpm; 100-235: ±2%
Data record	72-hour	72-hour
Transmission mode	USB	USB
	GPRS	
Operating temperature	5℃~40℃	5℃~40℃
Relative humidity	≤80%	≤80%
Sensor	M-50G	M-50G
SpO2 module	CSN604	CSN604

7. Intended use

The MD300W4 wrist pulse oximeter is a portable non-invasive device intended for spot checking ,data collection and recording of arterial oxygen saturation (SpO2) and pulse rate of adult and pediatric patient at home and hospital(including clinical use in internist/ surgery, Anesthesia, intensive care and etc).

8. Non-clinical Test

The MD300W4 wrist pulse oximeter is designed, tested and will be manufactured in accordance with both mandatory and voluntary standards, including:

- IEC 60601-1:1988+A1:1991+A2:1995, Medical Electrical Equipment – Part1: General requirements for safety.
- IEC 60601-1-2:2007, Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance, Collateral standard: Electromagnetic compatibility – Requirements and tests.
- ISO 9919:2005, Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use
- FCC 47 CFR Part 15B, Part 22 Subpart H and Part 24 Subpart E
- ANSI/IEEE Std. C95.1-1992 in accordance with the requirements of FCC Report and Order: ET Docket 93-62, and OET Bulletin 65 Supplement C

The Software Validation is in compliance with FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

The compatibility of the skin-contact component material in the finished product meets the requirement of Biocompatibility. The Biological Evaluation Tests are in compliance with the standards of ISO 10993, "Biological Evaluation of Medical Devices".

The test results indicate that the safety and effectiveness of the proposed devices is identical to that of the predicate device.

9. Clinical Test

The clinical test is conducted according to ISO9919:2005 Annex EE in Yue Bei Pepople's Hospital. 12 health adults are selected as the subjects. The system is evaluated during steady state / non-motion conditions with various levels of induced hypoxia resulting in stable oxygen saturation levels between 100% and 70% SaO2. The SpO2 are compared to arterial blood sample oxygen saturation (functional SaO2) as measured by CO-Oximetry.

There are no adverse events during the study. It can be determined from the study results that the SpO2 accuracy of the proposed device is compliance to the specification claimed by the manufacturer compared with "Golden Standard" Co-Oximeter. So the proposed device is safe and effective as well as the predicate device.

The accuracy claimed by the manufacturer is identical to that of the predicate device. And the test result indicates that the safety and effectiveness of the proposed devices is identical to that of the predicate device.

10. Substantial Equivalence Determination

According to the non-clinical and clinical test results, the proposed devices are as safe, as effective and perform as well as the predicate device. So the proposed devices are Substantially Equivalent (SE) to the predicate device which is US legally market device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 4, 2013

Mr. Lei Chen
Quality Director
Beijing Choice Electronic Technology Company, Limited
No. 9 Shuangyuan Road, Badachu Hi-Teeh Zone, Shijingshan District
Beijing, China 100041

Re: K122046
Trade/Device Name: Wrist Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: January 28, 2013
Received: January 28, 2013

Dear Mr. Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

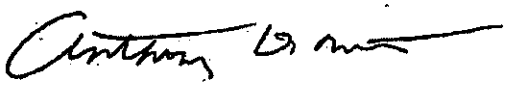
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit A Indications for Use

510(k) Number (if known): K122046

Device Name: Wrist Pulse Oximeter

Indications for Use:

The MD300W4 wrist pulse oximeter is a portable non-invasive device intended for spot checking ,data collection and recording of arterial oxygen saturation (SpO2) and pulse rate of adult and pediatric patient at home and hospital(including clinical use in internist/ surgery, Anesthesia, intensive care and etc).

Prescription Use __√__ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Lester W. Schultheis Jr
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(Division Sign-Off)
Division of Anesthesiology. General Hospital
Infection Control, Dental Devices

510(k) Number: K122046